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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,878	01/25/2001	John E. Sims	2976-B	7821

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EXAMINER
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ART UNIT	PAPER NUMBER
1647	

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Please find below and/or attached an Office communication concerning this application or proceeding.

File copy

Office Action Summary

Application No.	Applicant(s)
09/769,878	John E. Sims
Examiner	**Art Unit**
Fozia Hamud	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jun 10, 2002*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above, claim(s) *8, 9, and 18-31* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-7 and 10-17* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1a. Applicant's election of Group I (claims 1-17, in Paper No.6, filed on 10 June 2002 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

1b. Upon further consideration, the examiner has decided to re-restrict the following inventions.

I. Claims 1-7, 10-17, drawn to an isolated DNA comprising SEQ ID NO: 3, which encodes the polypeptide comprising the amino acid sequence of SEQ ID NO: 4, an expression vector, a host cell and a method of making the encoded protein, classified 435, subclass 69.1.

II. Claim, 1 drawn to an isolated DNA comprising SEQ ID NO:1, which encodes the polypeptide comprising the amino acid sequence of SEQ ID NO:2, classified 435, subclass 23.5.

III. Claims 1, 8-9, drawn to an isolated DNA comprising SEQ ID NO:14, which encodes the polypeptide comprising the amino acid sequence of SEQ ID NO:15, classified 435, subclass 23.5.

Inventions I-III are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent use, that is distinct for each invention which cannot be exchanged. Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another.

These sequences are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C.121, (MPEP § 803.04).

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has prima facie shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

2. During a telephone conversation with Janis Henry on 13 August 2002, a provisional election was made with traverse to prosecute the invention of Group I (claims 1-7, 10-17, i.e, SEQ ID NO:3 encoding SEQ ID NO:4). Affirmation of this election must be made by applicant in responding to this Office action.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventor ship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventor ship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

FR 8/20/02

Claims 8-9, 18-31 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention. Claims 1 (in part), 2-7, 10-17 are drawn to the elected invention.

Specification

3a. The disclosure is objected to because on page 50, line 25, it contains an embedded hyperlink. Applicants are required to delete the embedded hyperlink. Please examine the specification carefully for any other hyperlinks in the text and delete them. See MPEP §608.01.

Claim objections

3. Claim 1 is objected to because of the following informalities:

Claim 1 is objected to, because it recites non-elected SEQ ID NO:1 and SEQ ID NO: 14.

Claim Rejections - 35 U.S.C. § 101/112

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4a. Claims 1-7 and 10-17 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 1-7 and 10-17 of the instant invention are directed to an isolated nucleic acid molecule comprising SEQ ID NO:3, encoding the protein comprising the amino acid sequence set forth in SEQ ID Nos: 4. The specification defines the protein encoded by the claimed nucleic acid as being a human interleukin-1 family ligand (FIL-1-theta), (see page 9, lines 10-14). However, the

instant specification does not disclose any information regarding functional characteristics or the biological activity of the protein encoded by the claimed nucleic acid molecule. Instant specification discloses that the protein encoded by the claimed nucleic acid shares homology to other members of the interleukin -1 proteins, (see table 1 on page 9). Instant specification asserts that the claimed nucleic acid encodes a member of IL-1 family, and may display the following IL-1 activities; inhibit and/or activate the activation of vascular endothelial cells and lymphocytes, inhibit and/or stimulate macrophage and endothelial cells to produce IL-6, induce and/or inhibit the up regulation of prostaglandins, nitric oxide synthetase, induce and/or inhibit the induction of inflammatory mediators such as transcription factors NF-kB and AP-1, MAP kinases JNK and p38, COX-2, iNOS, and all activities stimulated by these molecules, (see page 7, lines 23-33). However, the specification does not demonstrate that the polypeptide encoded by the claimed nucleic acid actually displays any of these activities. Instant specification states that the FIL-1 theta polypeptide binds to FIL-1 theta receptor, and provides a general binding assay procedure, and the specification goes on to state that cells expressing FIL-1 theta receptors will show significantly enhanced binding of FIL-1 theta, (see Example 5 on pages 60-61). However, it is unclear from that example, whether these FIL-1 theta polypeptides actually bind to said receptors. Furthermore, instant specification does not disclose whether the polypeptide encoded by the claimed nucleic acid binds to its own specific receptor or whether it binds to the common IL-1 R, to which IL-1 α and IL-1β bind.

The state of the art is such that functional information can be automatically derived from structural information only to a limited extent, (see Sklonick et al, Nature Biotechnology, Vol.18,

No.3, pages 283-287, especially page 286, middle of column 1). Sklonick et al also state that knowledge of the overall structure or domain family is still not enough to confidently assign function to a protein. Therefore, there is little doubt that, after further characterization, if the instant polynucleotide and the protein it encodes are found to be members of the IL-1 family, they would have a specific, substantial and credible utility. However, further characterization is part of the invention and until it had been undertaken, the claimed invention is not supported by a specific asserted utility or a well established utility. The claimed invention is directed to a polynucleotide encoding a polypeptide of as yet undetermined function or biological significance. Thus, since there is no biological activity disclosed for the protein encoded by the claimed nucleic acid, the claimed invention is not supported by either a specific and substantially asserted utility or a well established utility.

4b. Claims 1-7 and 10-17 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantially asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Instant specification does not disclose any biological activity for the protein encoded by the claimed nucleic acid, therefore, there is no specific and substantial asserted utility or well established for the claimed nucleic acid or the encoded protein. The fact that the claimed nucleic acid encodes a protein that has homology to members of the IL-1 proteins is not sufficient to establish a specific and substantially asserted utility or a well established utility for it.

Should Applicants establish an activity for the polypeptide of SEQ ID NO: 4 encoded by the polynucleotide of SEQ ID NO: 3, instant specification would still fail to adequately describe and enable an isolated polynucleotide comprising a DNA that is at least 80% or 85 % to the polynucleotide of SEQ ID NO: 3 that encodes the polypeptide of SEQ ID NO: 4. Applicants do not teach which regions of said polynucleotide are critical to encode a functional polypeptide. The specification does not provide the requisite examples nor a representative number of different sequences that would allow the skilled artisan to produce a polynucleotide having at least 80% or 85% sequence identity to SEQ ID NO:3, which encodes the polypeptide of SEQ ID NO:4, nor does the disclosure provide criteria that explicitly enable such critical features. There is no guidance in the specification as to how one of ordinary skill in the art would generate a polynucleotide or a polypeptide encoded thereby, other than that exemplified. The issue here is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record.

In summary, the amount of experimentation required for one of ordinary skill in the art to use the claimed invention, an isolated polynucleotide comprising a DNA that is at least 80% or 85 % to the polynucleotide of SEQ ID NO: 3, encoding the polypeptide of SEQ ID NO: 4, or a polynucleotide that encodes a fragment that has IL-1 activity, would be undue. To practice the instant invention in a manner consistent with the breadth of the claims would not require just a repetition of the work that is described in the instant application but a substantial inventive contribution on the part of a practitioner which would involve the determination of those nucleotide

sequences of the disclosed naturally-occurring nucleic acid, which are required for functional and structural integrity of the claimed nucleic acid. It is this additional characterization of the disclosed nucleic acid that is required in order to obtain the functional and structural data needed to permit one to produce a nucleic acid which meets both the structural and functional requirements of the instant claim that constitutes undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 7 and 10 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5a. Claims 7 and 10 recite "an isolated DNA comprising a fragment of a DNA that encodes....., wherein the fragment has IL-1 activity...", however, it is unclear whether the claimed DNA fragment has IL-1 activity or whether a fragment of the encoded polypeptide has said activity. Furthermore, it is unclear which IL-1 activity is being referred to by the claims. The meets and bounds of the claims can not be ascertained. Appropriate correction is required.

Claim rejections-35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> ***A person shall be entitled to a patent unless -***
>
> (e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

6a. Claims 1-7, 10-17 are rejected under 35 U.S.C *§ 102*(e) as being anticipated by Ballinger et al (U.S. Patent 6,339,141).

Ballinger et al disclose an isolated polynucleotide that shares 99.3% with instantly claimed polynucleotide comprising the nucleotide sequence set of SEQ ID NO: 3. The polynucleotide taught by Ballinger et al encodes a polypeptide that shares 100% homology to the polypeptide of SEQ ID NO:4, claimed in the instant application. See attached copies of the comparison of instant SEQ ID Nos:, 3 and 4, claimed in the instant invention and the sequences of the references (SEQUENCE COMPARISON 'A-B', respectively). The polynucleotide taught by Ballinger et al encodes a polypeptide that has the amino acid threonine at position 44 and the amino acid aspartic acid at position 51. Therefore Ballinger et al reference anticipates instant claims 1-7, 10-17, because it meets all recited in claim 1 (g, h, j, k, l), 2-7, 10-17, in the absence of any evidence to the contrary.

Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Thursdays from 7:30 AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647
20 August 2002

Prema Mertz
PREMA MERTZ
PRIMARY EXAMINER